



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Randall Y. Grimes

Application No. : 09/981,406

Filed : October 17, 2001

Entitled : **DEVICES AND METHODS FOR
PERCUTANEOUS MITRAL VALVE REPAIR**

Docket No. : 22727-68

Group Art Unit: 3731

Examiner: U. T. Ho

Certificate of Mailing (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service Post Office as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date set forth below.

August 30, 2004

By:

Date of Signature and Mail Deposit

Lisa J. Michaud, Reg. No: 44,238
Attorney for Applicant(s)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF RANDALL Y. GRIMES
PURSUANT TO 37 C.F.R. §1.131

Dear Sir:

I, Randall Y. Grimes, residing at 315 Ivy Brooke Court, Atlanta, Georgia 30342, am the sole inventor of the above-referenced patent application, and I hereby declare as follows:

1. As the sole inventor of the subject matter claimed in this patent application, I am familiar with the patent application and its claims, as well as the development of the claimed invention. I understand that an Office Action mailed on May 28, 2004, rejects claims 1-6, 8-14, 17-18, 21, 27, and 28 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,629,534 of St. Goar et al. ("St. Goar").

BEST AVAILABLE COPY

2. At the time the above-referenced application was filed, I was a cardiology fellow at Massachusetts General Hospital ("MGH"), based in Boston, Massachusetts.

3. I understand that the St. Goar patent, which is cited against this patent application by the Examiner in the Office Action mailed on May 28, 2004, has a United States filing date of April 7, 2000. This application claims priority to provisional patent application No. 60/128,690 filed on April 9, 1999, which is the 102(e) critical filing date. I believe that the facts set forth below evidence that the invention claimed in this patent application was completed prior to April 7, 2000, which is the earliest priority date that could possibly be claimed by the St. Goar patent.

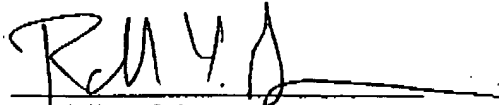
4. Before April 9, 1999, I prepared drawings and notes of the invention, a redacted copy of which is attached hereto as Exhibit A. These drawings and notes were sent, via facsimile, to an individual at Georgia Tech Research Corporation, which is the co-assignee of the above-referenced patent application. The facsimile transmittal is dated (redacted) prior to April 9, 1999. The notes describe and the drawings illustrate the details of the invention, and in particular they show a method of repairing a mitral valve using suction. I also prepared additional notes and drawings, a redacted copy of which is attached hereto as Exhibit B. These notes and drawings, which also describe the details of the invention, are dated (date redacted) prior to April 9, 1999.

5. All of these acts relating to the conception and completion of this invention took place in the United States.

Serial No.: 09/981,406
Group Art Unit: 3731
Examiner: U. T. Ho
Atty. Docket No.: 22727-68

6. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 8/30/04


Randall Y. Grimes

1356856.1

Exhibit A



CARDIAC ULTRASOUND LABORATORY, Vincent-Burnham 5
MASSACHUSETTS GENERAL HOSPITAL
Boston, Massachusetts 02114-2698

MGH Mail Address: VBK508

Tel. (617) 726-8871; 724-1995/7738 (staff physicians' offices)

Fax (617) 726-8383

FAX COVER SHEET

DATE: [REDACTED]

TO: Yogurtlan

FROM: RYM

Comments:

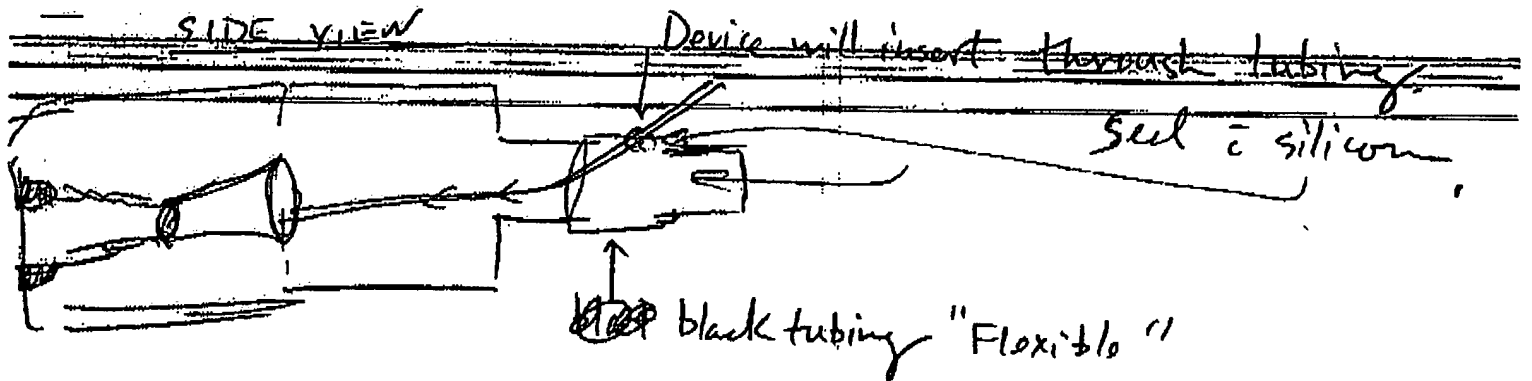
① Sunday PM will be
Ok for me.

② Wed PM, Thursday or well.

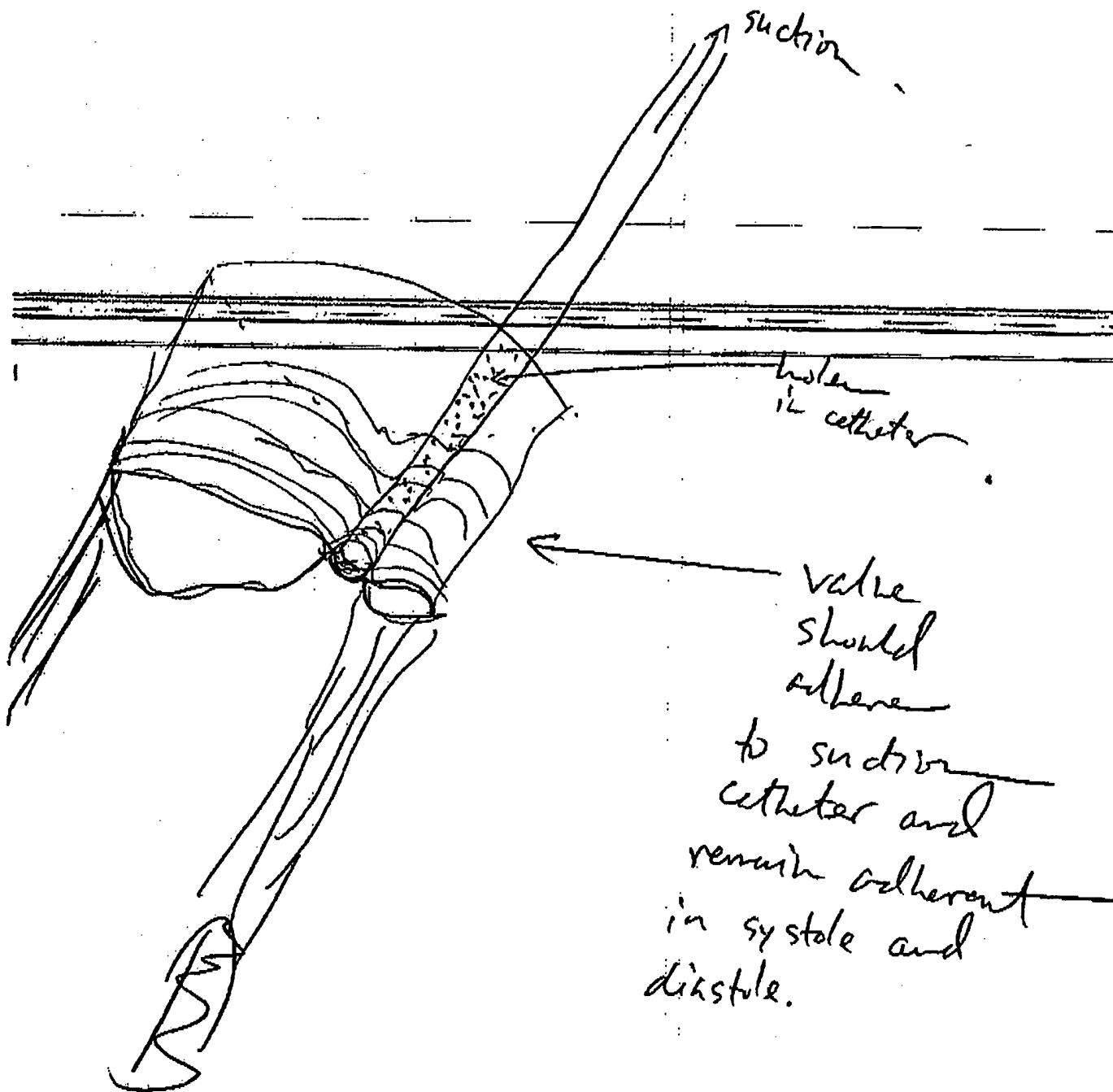
Pages to follow 3

PHASE 1

- ① Need a way to ~~access~~ access the mitral valve from the "atrial" side of your system.

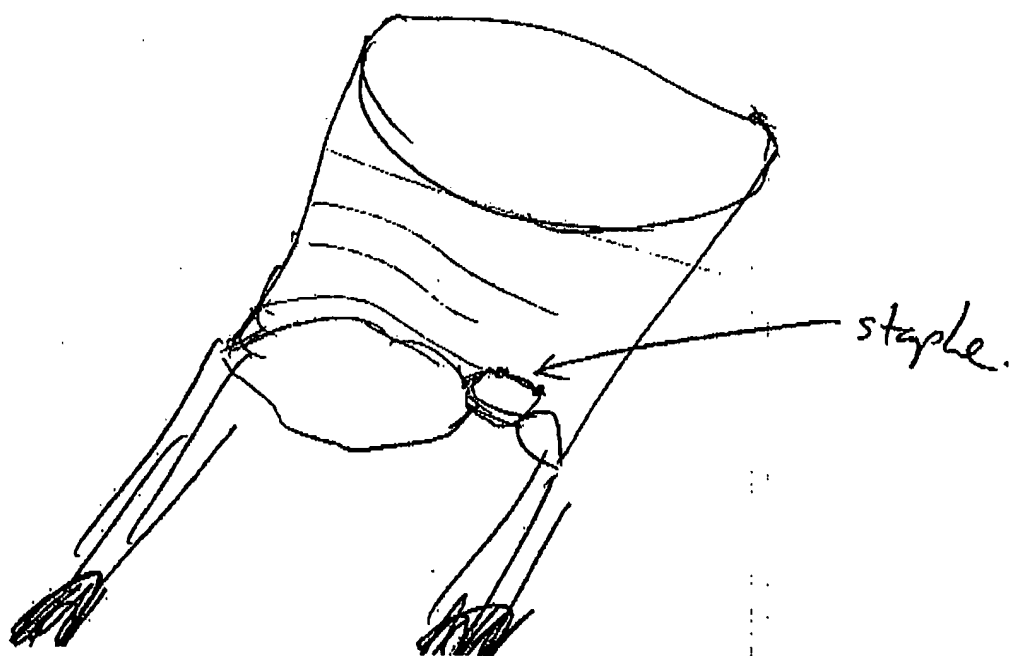


- ② I will bring a pre-fabricated device to Atlanta to ~~do the~~ test & "if suctioning can hold the valve stationary during the life of suction"
- ③ We will need a rota pump set up to provide suction
- ④ We will need to be able to ECHO the MR jet, etc. also video of the procedure.



PHASE 2

- ① This will not involve the suction device
- ② It is designed to test whether simply "stapling" the leaflets together eliminates MR 2° to prolapse
- ③ Set paps machine in a position that creates prolapse. 1 MR by ECLT2.
- ④ Then, open flow model, and simply staple the leaflets together, and re-ECLT2.



*** ACTIVITY REPORT ***

TRANSMISSION OK

TX/RX NO.

3214

CONNECTION TEL

914048942291

CONNECTION ID.

GEORGIA TECH

START TIME

[REDACTED]

USAGE TIME

01'53

PAGES

4

RESULT

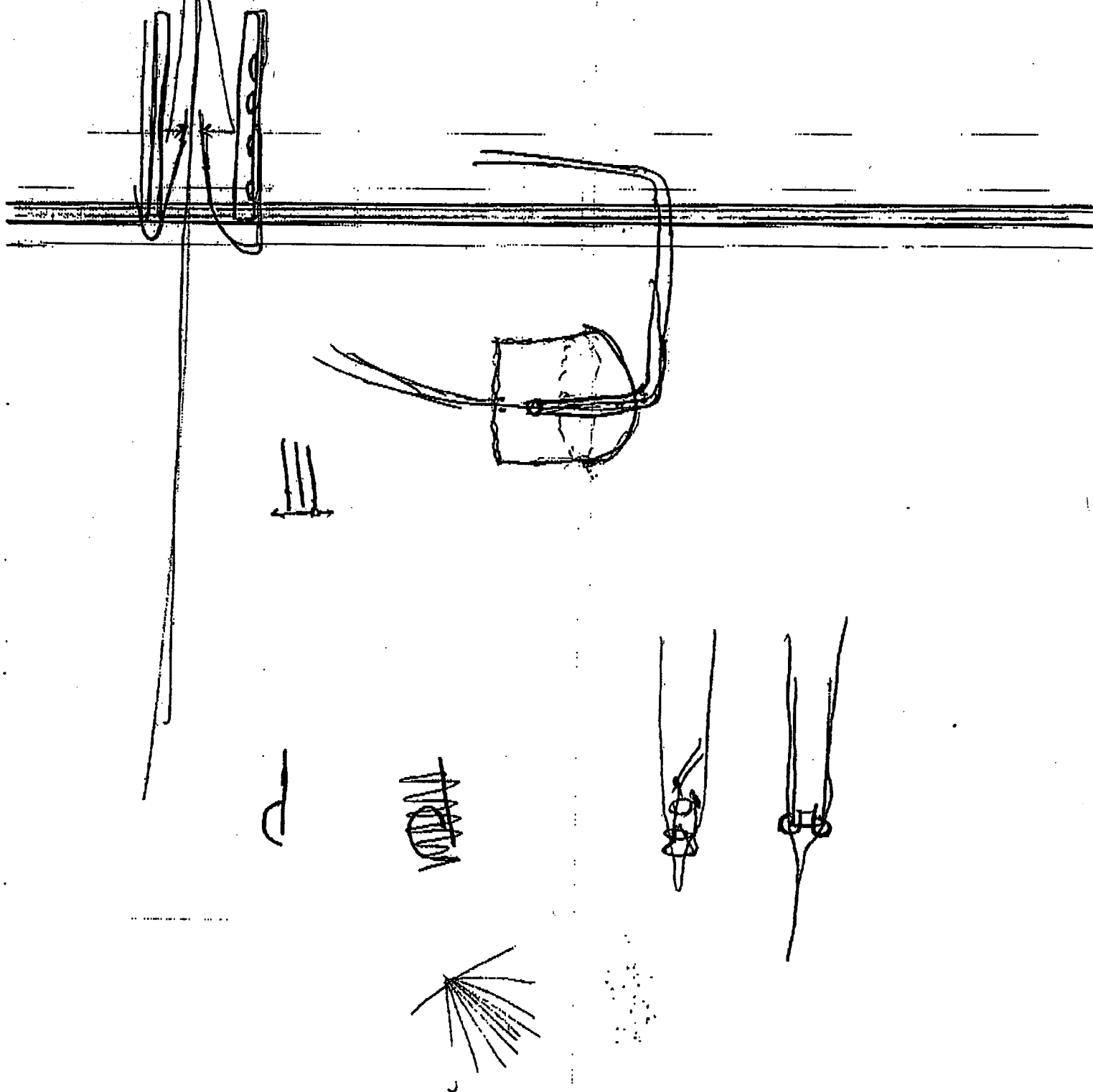
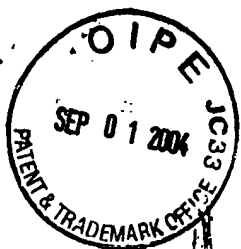
OK

Summary

① The valve suction device appears to be very reasonable.

② The ventricular staple, I believe, will not work b/c chordae would be in the way. "This may not be a problem w/ flat leaflet".

③ It would seem that a repair from the inner surface of the leaflets would be superior.



**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☒ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.